REMARKS

This Amendment, filed in reply to the Office Action dated December 11, 2008, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 5, 6 and 27-44 are rejected. Claims 5, 37, 38, 40, 41 and 45 are amended herewith. Support for the amendment to Claim 5 can be found throughout the specification as originally filed, and at, for example, the paragraph bridging pages 9 and 10, and Examples 1-8. Claims 37, 38, 40 and 41 are amended herewith solely to further clarify Applicants' claimed invention. Claim 45 is amended herewith to provide proper antecedent basis.

No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

Information Disclosure Statements

Applicants thank the Examiner for returning a signed copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed June 4, 2008, indicating consideration of the references therein.

Claim to Priority

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority, and for acknowledging receipt of a certified copy of Applicants' foreign priority document from the International Bureau.

Claims 34, 37, 38, 40 and 41 are Enabled under 35 U.S.C. §112

1. In one aspect of the rejection, set forth on page 3 of the Office Action, the Examiner rejects Claims 37, 38, 40 and 41 as lacking enablement for an antibody containing fewer than 6 complementarity determining regions (CDRs).

The Examiner contends that the state of the art at the time of the invention was such that it would be highly unpredictable whether an antibody containing less than six CDRs would exhibit the same binding specificity, or bind to the same antigen, as the corresponding antibody containing all 6 CDRs.

Whilst Applicants maintain that one of skill in the art would readily appreciate that antibodies containing only CDRs from a heavy or light chain can be produced without undue experimentation, and that such antibodies can bind to the same antigen as the parent antibody molecule containing 6 CDRs, solely to advance prosecution, and without acquiescing to the merits of the rejection, Applicants herewith amend Claims 37, 38, 40 and 41 to recite that the recombinant antibody contains a heavy chain variable region and a light chain variable region. Applicants respectfully submit that the amendments overcome this aspect of the rejection.

2. In a second aspect of the rejection, Claim 34 is rejected as lacking enablement for an antibody which specifically binds to the epitope bound by the monoclonal antibody produced by the KM2160 hybridoma. The Examiner acknowledges Applicants' deposit of hybridoma clone KM2160, on August 12, 2004, with the International Patent Organism Depository, National Institute of Advanced Industrial Science and Technology, AIST Tsukuba Central 6, 1-1, Higashi 1-chome Tsukuba-shi, Ibaraki, Japan, which was accorded Accession Number FERM BP-10090. However, the Examiner asserts that the record does not provide the requisite

assurances to satisfy the enablement requirement of §112, first paragraph. The Examiner expressly indicates that providing such assurances would obviate the rejection of Claim 34.

Initially, Applicants reiterate that the specification as filed discloses the precise polypeptide structures of the heavy and light chain variable regions (*i.e.*, SEQ ID NOs: 16 and 18, respectively) of a humanized antibody that may be used to practice the invention claimed in Claim 34, and that such, when coupled with the maturity of recombinant antibody technology at the time of the invention, would allow one of skill in the art to produce a humanized antibody having these heavy and light chain variable regions without undue experimentation.

Nevertheless, in the interest of advancing prosecution, and without acquiescing to the merits of the rejection, Applicants submit herewith a Statement of Availability pertaining to the KM2160 hybridoma. Applicants respectfully submit that the concurrently-filed Statement of Availability overcomes this aspect of the rejection.

Withdrawal of the enablement rejections is respectfully requested.

Claims 5, 6 and 27-46 are Patentable under 35 U.S.C. §102

On page 6 of the Office Action, the Examiner rejects Claims 5, 6 and 27-46 under 35 U.S.C. § 102(b) as being anticipated by Shitara *et al.*, essentially for reasons of record.

In response to Applicants' previous arguments, the Examiner asserts that Claim 5, provided its broadest reasonable interpretation, encompasses an antibody *conjugated* to an agent.

Initially, Applicants note that Claims 45 and 46 are included in the rejection, although these claims are indicated as being withdrawn from consideration on the Office Action Summary Page. Nevertheless, in the interest of compacting prosecution, Applicants address the rejection as it applies to all of Claims 5, 6 and 27-46.

Turning to the substance of the rejection, Applicants note that Claim 5 is amended herewith to recite that "said agent is not conjugated to said antibody or antigen-binding fragment." Support for the amendment to Claim 5 can be found throughout the specification as originally filed, such as, for example, at page 9, lines 17-22, wherein Applicants disclose administration of a recombinant antibody and an agent in combination, either simultaneously or successively (*i.e.*, as separate components), and in Examples 1-8. Further support can be found in the paragraph bridging pages 9 and 10 of the specification as filed, wherein Applicants disclose that, in addition to administration of the recombinant antibody and agent as separate components, the agent may alternatively be bound to the recombinant antibody (*i.e.*, conjugated) to form a fusion antibody. If alternate elements are positively recited in the specification, they may be explicitly excluded in the claims. See MPEP § 2173.05(i); *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) and; *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). Thus, consistent with relevant case law, Applicants' proviso is fully compliant with the provisions of §112, and fully supported by the specification as originally filed.

Applicants note that the portion of Shitara *et al.* relied upon by the Examiner only contemplates the conjugation of a radioisotope, protein or agent to an antibody, and such is excluded by the claims as amended. Accordingly, Shitara *et al.* fails to teach each and every element of the presently claimed invention, as is required to maintain a rejection under section 102.

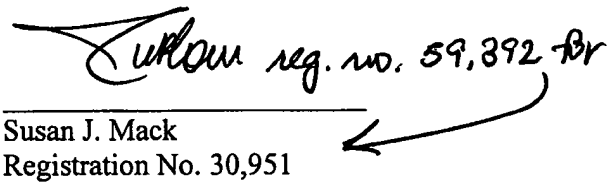
Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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